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ATTORNEY DOCKET NO. FIRST NAMED INVENTOR APPLICATION NO. FILING DATE 515-4167 R 07/12/00 GIORGI 09/355,210 **EXAMINER** HM22/0323 LUKTON, D JAMES V COSTIGAN PAPER NUMBER **ART UNIT** HEDMAN GIBSON & COSTIGAN 1185 AVENUE OF THE AMERICAS 1653 NEW YORK NY 10036-2601

DATE MAILED:

03/23/01

Please find below and/or attached an Office communication concerning this application or proceeding.

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Please find below a communication from the EXAMINER in charge of this application.

Commissioner of Patents

Please see the attached communication regarding applicants' response to the restriction.

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Applicants' communication filed 3/16/01 is **non-responsive** to the restriction mailed 2/13/01. As indicated previously a restriction is required as follows:

- I. Claims 1-3, 5-9, drawn to compounds.
- II. Claim 4, drawn to a method of making the compounds of Group I.
- III. Claims 10-14 drawn to a method of using the compounds of Group I.

In addition to the foregoing, applicants are required under 35 U.S.C. §121 to elect a disclosed specie for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. A "specie" is a specific compound, with all substituent variables accounted for.

Applicants have suggested that an examiner can assert lack of unity. The examiner herewith asserts lack of unity. Consider the following passage from the MPEP:

MPEP 1850

PCT Rule 13.2, as it was modified effective 01 July 1992, no longer specifies the combinations of categories of invention which are considered to have unity of invention. Those categories, which now appear as a part of Annex B to the Administrative Instructions, has been substituted with a statement describing the method for determining whether the requirement of unity of invention is satisfied.

Unity of invention exists only when there is a technical relationship among the claimed inventions involving one or more special technical features. The term "special technical features" is defined as meaning those technical features that define a contribution which each of the inventions considered as a whole, makes over the prior art.

The determination is made based on the contents of the claims as interpreted in light of the description and drawings. Annex B also contains examples concerning unity of invention.

Independent and Dependent Claims.

Unity of invention has to be considered in the first place only in relation to the independent claims in an international application and not the dependent claims. By "dependent" claim is meant a claim which contains all the features of another claim and is in the same category of claim as that other claim (the expression "category of claim" referring to the classification of claims according to the subject matter of the invention claimed for example, product, process, use or apparatus or means, etc.).

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If the independent claims avoid the prior art and satisfy the requirement of unity of invention, no problem of lack of unity arises in respect of any claims that depend on the independent claims. In particular, it does not matter if a dependent claim itself contains a further invention. Equally, no problem arises in the case of a genus/species situation where the genus claim avoids the prior art. Moreover, no problem arises in the case of a combination/subcombination situation where the subcombination claim avoids the prior art and the combination claim includes all the features of the subcombination.

If, however, an independent claim does not avoid the prior art, then the question whether there is still an inventive link between all the claims dependent on that claim needs to be carefully considered. If there is <u>no link remaining</u>, an objection of <u>lack of unity</u> (that is, arising only after assessment of the prior art) may be raised. Similar considerations apply in the case of a genus/species or combination/subcombination situation.

The examiner asserts, without evidence at this point, that some of the compounds of claim 1 have been disclosed in the prior art, and that claim 1 does not define a contribution over Accordingly, unity of invention is lacking. However, if the examiner the prior art. ultimately fails to provide evidence that one or more of the compounds of claim 1 have been disclosed in the prior art, he will be compelled to rejoin Groups II and III for further Were an examiner to refuse to rejoin method-of-making and method-of-use examination. claims in a §371 application when the claimed compounds were clearly novel, any petition of the restriction submitted after the examination had been completed would be decided in If it turns out that, e.g., 90% of the compounds of Group I are novel, applicants favor. rejoining will still take place, but the structural limitations on Group I will have to extend Given that rejoining of Groups II and III will be required if to Groups II and III as well. Group I proves to be novel, the basis of applicants' concern is not evident. While rejoining of Groups II and III with (the novel compounds of) group I will ultimately take place, applicants are still required to elect a Group and a specie.

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The time for response is now 30 days from the mailing of this Office action. Failure to elect a Group and a specie in response to this Office action will result in **ABANDONMENT** of the application.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton. Phone: (703) 308-3213.

An inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

DAND LUKTOR PATENT EXAMPLER GROUP 1800